DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 14, 2015

Symmetry Surgical
c/o Mr. David Furr
Regulatory Affairs Consultant
FDC Services
8708 Capeheart Cove
Austin, TX 78733

Re: K143078
Trade/Device Name: Bookwalter Gordon Adjustable Compression Element
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: April 1, 2015
Received: April 3, 2015

Dear Mr. Furr,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Bookwalter Gordon Adjustable Compression Element

Indications for Use *(Describe)*
The Bookwalter Gordon Adjustable Compression Element is indicated for use to provide hemostasis of the femoral vascular access site, during and following catheterization or cannulation procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary Pursuant to 21 CFR 807.92

K143078

Date: May 13, 2015

1. Submitted By: Symmetry Surgical Inc.
3034 Owen Drive
Antioch, TN 37013
1-800-251-3000

2. Contact: David C. Furr
FDC Services, LLC
8708 Capehart Cove
Austin, Texas 78733
512-906-9654

3. Product: Bookwalter Gordon Adjustable Compression Element

DXC - Class II (21 CFR 870.4450)

4. Common/Trade Name: Vascular Clamp
Bookwalter Gordon Adjustable Compression Element

Description:

The Bookwalter Gordon Adjustable Compression Element is an adjustable metal compression device that provides an alternative to applying direct hand pressure to obtain hemostasis during vascular catheterization procedures. The device is secured to a surgical table by means of a compatible clamp which supports an articulating arm that allows positioning of the "metal hand" over the vascular access site. The hand has "fingers" that can be adjusted separately to apply compressive pressure to particular locations around the vascular access site. Once in place the Adjustable Compression Element remains securely in position thereby providing ongoing compression without intervention by the surgical staff although it can be adjusted at any time if so desired. The device is reusable and can be cleaned and sterilized in the hospital setting. The Adjustable Compression Element is constructed of high strength stainless steel for rigidity and durability during use. The system also has an available sterilization container to ensure effective reprocessing.

Intended Use:

The Bookwalter Gordon Adjustable Compression Element is indicated for use to provide hemostasis of the femoral vascular access site, during and following catheterization or cannulation procedures.

Technological Characteristics:

The Bookwalter Gordon Adjustable Compression Element consists of a Left Finger Subassembly, a Right Finger Subassembly, and a Center Block Subassembly which can be mounted onto an adjustable table mounted arm. The principal material of construction is 17-4 PH SS, which is hardened stainless steel. The adjustable arm and finger paddles can be positioned independently and locked into place to achieve the correct level of compression. Hemostasis is achieved through mechanical compression.

In comparison to the predicate device, the use of mechanical compression for hemostasis is the same. Both devices are mounted on an arm and feature adjustable height and pressure settings. The arm components are constructed of rigid materials and table mounted at the patient's side. The Bookwalter Gordon Adjustable Compression Element has a re-usable finger assembly as compared to a disposable circular disc or finger assembly on the predicate device.

The product has been evaluated to ensure that it meets mechanical requirements, biocompatibility needs, cleaning, sterilization and drying time.

Testing included the following:

Mechanical Performance, including:

- Maximum compression force
- Expanding & contracting under full load
- 2X force load

Steam Sterilization Efficacy Validation
Dry Time Validation
Cytotoxicity

The mechanical performance testing for maximum compression force, expanding and contracting under full load, and 2X force load test demonstrate that the subject device is capable of continuous compression without bending, breaking, or loosening. This testing demonstrates that the product is capable of performing compression and thereby hemostasis in the same manner as the predicate device.

Substantial Equivalence:

The design and function of the Bookwalter Gordon Adjustable Compression Element has been determined to be substantially equivalent to the CompressAR SuperComfort Disc and StrongArm SuperComfort System from Advanced Vascular Dynamics (K040615). Both products have the same indications for use and perform in a similar manner.

Conclusion:

Based on results of mechanical testing, basic design and function, the Bookwalter Gordon Adjustable Compression Element has been determined to be substantially equivalent to the CompressAR SuperComfort Disc and StrongArm SuperComfort System. The device provides sufficient compression to achieve hemostasis and can be mounted, positioned, and adjusted in a manner similar to the predicate. Validation testing for sterilization of all re-usable components has been completed successfully and cleaning rationale provided. Instructions provide user information for use, cleaning, and re-use.